

REMARKS

The Office Action of May 21, 2003 has been received and considered. In the Office Action, claims 1 and 6, 7, 9 and 10 were rejected under either 35 U.S.C. §102 or §103. Claim 8 has not been rejected in the outstanding Office Action. As a result, it is believed that claim 8 is allowable over the prior art. Notice of such is requested.

Claim 1 has been cancelled. Claims 6, 9 and 10 have been amended. Claim 12 has been added. Claims 6-10 and 12 remain pending. Reconsideration and allowance of the instant application are respectfully requested.

Claims 1, 6 and 7 were rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,248,615 to Keller that discloses a stabilized prolactin calibrator that can include a label such as dye particles. The patent to Keller is concerned with the stabilization and life of the prolactin calibrator. It does not discuss (1) the application of the prolactin to a breast duct or (2) a ductal access tool for introducing the prolactin calibrator into a breast duct.

Claim 1 has been cancelled. Claim 6 has been amended to recite (1) a ductal access tool sized to obtain a ductal fluid sample including ductal epithelial cells from within a breast duct and (2) an aliquot of a bioactive composition including a lactation-stimulating agent and one of the recited dyes or stains. As mentioned above, the patent to Keller clearly does not disclose any type of a tool for applying the prolactin calibrator to the body. Therefore, the patent to Keller cannot anticipate amended claims 6 and 7. Withdrawal of the rejection is requested.

Claim 6 has also been rejected under 35 U.S.C. §103(a) as being unpatentable over Keller in view of U.S. Patent No. 6,319,510 to Yates that discloses a gum pad for the topical or systemic application of pharmaceutical or nutritional agents. Like the patent to Keller, the patent

to Yates does not disclose a tool that is sized to be inserted into a breast duct and collect a ductal fluid sample from within the breast duct. Therefore, it would not have been obvious to one of ordinary skill in the art to modify the patent of Keller as suggested in the outstanding Office Action because the resulting combination would not arrive at the system recited in claim 6. Withdrawal of the rejection is requested.

Claims 9 and 10 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,059,586 to Collier et al. in view of Keller and Tabar et al. The patent to Collier is relied upon to disclose a method of inserting a blunt syringe into the teat of a cow and depositing a material in the teat cistern. While the patent to Collier teaches using a blunt syringe in the administration of an agent into the teat cistern of a cow, it does not teach an instrument that can be introduced into the breast duct of a human and retrieve ductal fluid cells from within the breast duct as discussed below.

Like the patent to Collier, the patent to Tabar discloses the insertion of an instrument into the breast duct and the introduction of a fluid (a contrast fluid) into the accessed breast duct. However, also like the patent to Collier, the patent to Tabar is not concerned with obtaining ductal fluids. Instead, Tabar only relates to introducing fluids into a duct. As a result, the patent to Tabar does not disclose a ductal access tool that is sized to retrieve a ductal fluid sample including ductal epithelial cells from within a breast duct.

It has long been known in the art that ductal access instruments such as those disclosed in the patents to both Collier and Tabar were not effective for removing ductal fluid samples including ductal epithelial cells from within a breast duct. This is evidenced by the discussion of previous attempts to retrieve a ductal fluid sample from within a breast duct using an indwelling

instrument set forth in the "Background of the Invention" section of U.S. Patent Application No. 09/473,510 (now U.S. Patent No. 6,413,228) that was incorporated by reference in the instant application. This is also evidenced by the disclosure of Dr. Susan Love, et al. in an article published in *The Lancet*¹ (copy supplied herewith). On page 998, column 2 of the article, Dr. Love discusses that human breast ducts are so small that it is difficult to aspirate back through an instrument that is used to deliver a fluid into the breast duct. Dr. Love discloses that during her method, the instrument used to introduce the wash fluid into the duct is removed before the ductal fluid sample is collected. After the tool is withdrawn from the duct, the ductal fluid samples are collected externally on the surface of the nipple. Therefore, it is clear from a review of the disclosures discussed in the "Background of the Invention" of U.S. Patent Application No. 09/473,510 and the express teachings of Dr. Love that the tools disclosed in the patent to Collier and Tabar cannot be fairly considered as the recited tool sized for accessing a breast duct and collecting a ductal fluid sample including ductal epithelial cells from within the breast duct.

The patent to Keller clearly does not disclose the recited ductal access tool as discussed above. Therefore, the modification asserted in the outstanding Office Action would not have been obvious to one of ordinary skill in the art for the resulting combination would not have arrived at the systems recited in claims 9, 10 and 12. Withdrawal of the rejection requested.


All rejections having been addressed, applicant respectfully submits that the instant application is in condition for allowance, and respectfully solicits prompt notification of the same. If any issues remain, the Examiner is requested to contact the undersigned at the below listed telephone number.

¹ "Breast-duct Endoscopy to Study Stages of Cancerous Breast Diseases", *The Lancet*, pp 997-999, October 12, 1996.

Appl. No.: 09/876,144
Amendment dated August 19, 2003
Reply to Office Action of May 21, 2003

It is believed that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly.

Respectfully submitted,
BANNER & WITCOFF, LTD.

By: 
Brian E. Hanlon
Registration No. 40,449

1001 G Street, N.W.
Washington, D.C. 20001-4597
Tel: (202) 824-3000
Fax: (202) 824-3001
Dated: August 19, 2003